

FEB - 1 2005

CoolTouch Corporation
Model CT3S Nd:YAG Laser System
510(k) Premarket Notification
510(k) SUMMARY

K 043046

Submitter: CoolTouch Corporation

Address: 9085 Foothills Boulevard
Roseville, CA 95747

Contact Person: Donald V. Johnson
Vice-President of Operations

Telephone: (916) 677-1912

Facsimile: (916) 677-1901

Date Prepared:

Device Trade Name: CoolTouch Corporation Model CT3S Nd:YAG Laser System

Common Name: Nd: YAG Surgical Laser

Classification Name: Laser Surgical Instrument.
21 C.F.R. § 878.4810

Legally Marketed Predicate Device: CoolTouch Corporation Model NS-160, CTEV.

Description of the CoolTouch Nd:YAG Laser Systems: The CoolTouch Nd:YAG Laser Systems are Nd:YAG lasers producing laser emission at 1320 nm. The lasers consist of three interconnected sections: The cabinet, which houses the power supply, cooling system, microcontroller and the laser, the fiber optic, and/or the handpiece.

Intended use of CoolTouch Nd:YAG Laser Systems: The intended use of the CoolTouch CT3S Nd:YAG Laser System is:
a) for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue,
b) for treatment of fine lines and wrinkles,
c) for treatment of back acne and atrophic acne scars,
d) for treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities.

Nonclinical Performance Data:	None
Clinical Performance Data:	Clinical trials also produced results that indicated that the CoolTouch Nd:YAG Laser Systems are effective in the treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities. See previous related 510(k) submissions for clinical results.
Conclusion:	<p>The CoolTouch CT3S Nd:YAG Laser System is indicated:</p> <ul style="list-style-type: none"> a) for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue, b) for the treatment of fine lines and wrinkles, c) for treatment of back acne and atrophic acne scars, d) for treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities.
Additional Information:	None requested at this time



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Donald V. Johnson
Vice President of Operations
CoolTouch Corporation
9085 Foothills Boulevard
Roseville, California 95747

Re: K043046

Trade/Device Name: CoolTouch CT3S Nd:YAG Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: January 21, 2005

Received: January 24, 2005

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Donald V. Johnson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Miriam C. Provost

for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K 043046

Device Name: CoolTouch CT3S Nd:YAG Laser System

Indications for Use:

The CoolTouch CT3S Nd:YAG Laser System is indicated:

- a) for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue,**
- b) for use in the treatment of fine lines and wrinkles,**
- c) for treatment of back acne and atrophic acne scars,**
- d) for treatment of reflux of the greater saphenous vein associated with varicose veins and varicosities.**

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Prescription Use ☒ OR K043046 Over-the-Counter Use ☐
510(k) Number K043046 (21 CFR 801.109)